

AN ORDINANCE

9 8 5 3 8

**AUTHORIZING THE EXECUTION OF A CLINICAL TRIAL AGREEMENT WITH NOVARTIS PHARMACEUTICALS CORPORATION PROVIDING UP TO \$139,600.00 FOR THE PERIOD OCTOBER 1, 2003 THROUGH SEPTEMBER 30, 2005 FOR THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT TO PARTICIPATE IN A CLINICAL TRIAL TO EVALUATE THE EFFECTIVENESS OF FAMVIR®, A MEDICATION FOR THE TREATMENT OF RECURRENT GENITAL HERPES IN ADULTS; ESTABLISHING A FUND; ADOPTING THE PROJECT BUDGET; AND AUTHORIZING PAYMENTS FOR CONTRACTUAL SERVICES.**

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**WHEREAS**, the San Antonio Metropolitan Health District (SAMHD) delivers comprehensive public health services to protect the health of all residents and visitors within the jurisdiction of the SAMHD; and

**WHEREAS**, the SAMHD operates a Sexually Transmitted Disease (STD) Clinic that provides testing, diagnosis and treatment for sexually transmitted diseases and field investigations for partner notifications; and

**WHEREAS**, Novartis Pharmaceuticals Corporation (Novartis) has offered a Clinical Trial Agreement Protocol CFAM810A 2402 that will provide up to \$139,600.00 for the SAMHD to evaluate the effectiveness of Famvir®, an FDA approved medication for the treatment of recurrent genital herpes in adults; and

**WHEREAS**, the SAMHD desires to participate in this clinical trial that will: 1) allow patients to be more compliant with treatment; 2) be cost effective in the use of medications; 3) have less risk of unwanted side effects; 4) allow for control of an outbreak sooner and reduce the opportunity for spread of the disease; and 5) heal the lesions faster, and lessen the risk of spreading the disease to a newborn at delivery; and

**WHEREAS**, the SAMHD desires to reimburse the participants enrolled in the clinical trial for any expenses involving time and travel that may be incurred through their participation in this project; and

**WHEREAS**, it is now necessary to authorize the acceptance and execution of this agreement with Novartis, establish a fund, adopt the project budget, and approve the payment of stipends for participants; **NOW THEREFORE:**

**BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF SAN ANTONIO:**

**SECTION 1.** The City Manager, or her designee, is hereby authorized to accept and execute the Clinical Trial Agreement Protocol CFAM810A 2402 with Novartis Pharmaceuticals Corporation (Novartis) for the period October 1, 2003 through September 30, 2005, which will provide up to \$139,600.00 for the San Antonio Metropolitan Health District to participate in an evaluation of the effectiveness of Famvir®, an FDA approved medication for the treatment of recurrent genital herpes in adults. A copy of this agreement, in substantially correct form, is set out as Attachment II and incorporated herein for all purposes.

**SECTION 2.** Fund No. 26-012252 entitled "Novartis Famvir Protocol CFAM810A 2402 Study Project" is designated for use in accounting for the above program.

**SECTION 3.** The sum of \$139,600.00 is hereby appropriated in the above-designated fund for the Novartis Famvir Protocol CFAM810A 2402 Study Project, and the budget attached hereto and incorporated herein as Attachment I is hereby approved and adopted for entry on the City's books.

**SECTION 4.** Payments in an aggregate amount not to exceed \$8,275.00 are authorized to be paid to on-call contract licensed physicians as needed for weekend coverage at the Clinic. These payments will be made from Fund 26-012252, Activity Code 36-07-92, Index Code 784074 on a fee-for-service basis.

**SECTION 5.** Payments in an aggregate amount not to exceed \$3,000.00 are authorized to be paid out as stipends of up to \$25.00 per visit per participant in the clinical trial. These payments will be made from Fund 26-012252, Activity Code 36-07-92, Index Code 784637.

**SECTION 6.** The Director of Finance, may, subject to concurrence by the City Manager or the City Manager's designee, correct allocation to specific index codes and fund numbers as necessary to carry out the purpose of this ordinance.

**SECTION 7.** Should the clinical trial agreement offered be in an amount other than that budgeted for, or should the agreement contain terms and conditions different than those currently existing, acceptance of the agreement and budget will be subject to subsequent City Council ordinance.

**SECTION 8.** If an agreement, as first reviewed and approved by the City Attorney, is not signed by both parties within sixty (60) days from the effective date of this ordinance, it becomes null and void, and any further signed documents must be considered by the City Council.

**SECTION 9.** This ordinance shall be effective on and after the tenth (10<sup>th</sup>) day after passage hereof.

PASSED AND APPROVED this 4<sup>th</sup> day of December, 2003.

ATTEST: Mary Lou Rodriguez  
for City Clerk

Ed D. Garza  
MAYOR  
EDWARD D. GARZA

APPROVED AS TO FORM: [Signature]  
for City Attorney